

- 1: (Currently Amended) A unitized electronic time-temperature indicator device for rapidly assessing the acceptability of an external material's thermal history, said device containing computational means, and a temperature measurement means; wherein said device periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device;
- and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material; and wherein said computational ~~computing~~ means generate a running sum of said function of temperature over time;
- and wherein said function of temperature resides with said unitized device;
- and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material;
- and in which said running sum is compared to a reference value, and the result of said comparison is used to generate an output signal indicative of the fitness for use of said material.
- 2: (Original) The device of claim 1, in which the output signal is a visual output signal.
- 3: (Original) The device of claim 1, in which the output signal is chosen from the group of visual output signals, vibration signals, sonic signals, radiofrequency signals, electrical signals, or infra-red signals.
- 4: (Original) The device of claim 1, further containing means to enable the function of temperature and reference value to be automatically programmed into an assembled device.
- 5: (Original) The device of claim 1, in which the computational means is a microprocessor, the device is continually powered throughout its use lifetime, and the

power means is chosen from the group of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency means.

6: (Original) The device of claim 1, in which the function of temperature has a temperature resolution granularity of 10 °C or smaller, and the periodicity of sampling has a time resolution granularity of 2 hours or smaller.

7: (Original) The device of claim 1, in which the display means convey information pertaining to the fractional remaining stability lifetime of material that has not yet expired, or the fractional completion of a time-temperature dependent incubation reaction.

8: (Original) The time-temperature device of claim 1, incorporated into a material dispensing device, in which the time-temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history.

9: (Currently Amended) A unitized electronic time-temperature indicator device for rapidly assessing the acceptability of an external material's thermal history, said device containing computational means, and a temperature measurement means; wherein said device periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device; and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material; and wherein said computational ~~computing~~ means generate a running sum of said function of temperature over time; and wherein said function of temperature resides with said unitized device; and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material;

and in which said running sum is compared to a reference value, and the result of said comparison is used to generate a visual output indicative of the fitness for use of said material.

10: (Original) The device of claim 9, in which the function of temperature and reference value may be programmed into the assembled device by a replaceable memory chip, electronic data transfer, infrared data transfer, or radio frequency data transfer.

11: (Original) The device of claim 9, in which the computational means is a microprocessor, the device is continually powered throughout its use lifetime, and the power means is chosen from the group of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency means.

12: (Original) The device of claim 9, in which the function of temperature has a temperature resolution granularity of 10 °C or smaller, and the periodicity of sampling has a time resolution granularity of 2 hours or smaller.

13: (Original) The device of claim 9, in which the display means convey information pertaining to the fractional remaining stability lifetime of material that has not yet expired, or the fractional completion of a time-temperature dependent incubation reaction.

14: (Original) The time-temperature device of claim 9, incorporated into a material dispensing device, in which the time-temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history.

15: (Currently Amended) A unitized electronic time-temperature indicator device for rapidly assessing the acceptability of an external material's thermal history, said device containing computational means, and a temperature measurement means;

wherein said device periodically samples the temperature and computes a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device;

and wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material; and wherein said computational computing means generate a running sum of said function of temperature over time;

and wherein said function of temperature resides with said unitized device;

and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material; and in which said running sum is compared to a reference value, and the result of said comparison is used to generate a visual output indicative of the fitness for use of said material, and the device contains means to allow the function of temperature and reference value to be automatically programmed into an assembled device.

16: (Original) The device of claim 15, in which the function of temperature and reference value may be programmed into the assembled device by a replaceable memory chip, electronic data transfer, infrared data transfer, or radio frequency data transfer.

17: (Original) The device of claim 15, in which the computational means is a microprocessor, the device is continually powered throughout its use lifetime, and the power means is chosen from the group of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency means.

18: (Original) The device of claim 15, in which the function of temperature has a temperature resolution granularity of 10 °C or smaller, and the periodicity of sampling has a time resolution granularity of 2 hours or smaller.

19: (Original) The device of claim 15, in which the display means convey information pertaining to the fractional remaining stability lifetime of material that has not yet

expired, or the fractional completion of a time-temperature dependent incubation reaction.

20: (Original) The time-temperature device of claim 15, incorporated into a material dispensing device, in which the time-temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history.

21: (New) The device of claim 1, in which said function of temperature is a stability bank function.

22: (New) The device of claim 9, in which said function of temperature is a stability bank function.

23: (New) The device of claim 15, in which said function of temperature is a stability bank function.

24. (New) A unitized electronic time-temperature indicator device for rapidly assessing the acceptability of an external material's thermal history;
wherein the device contains a microprocessor, a temperature sensor, time monitoring means, and stability memory means;
said microprocessor and said time monitoring means controlling the time intervals between successive temperature sensor measurements;
said temperature sensor detecting a temperature environmental condition affecting the life of said material;
said stability memory means residing with said unitized device;
said stability memory means storing a function of temperature;
said function of temperature calculating the impact that the environmental temperature, over the interval of time between successive temperature sensor measurements, has on a detectable property of said material;
said function of temperature accepting the temperature environmental condition from the temperature sensor as an input;

said function of temperature using data retrieved from said stability memory means in conjunction with said microprocessor to calculate the numeric impact that said input temperature has on the detectable property of said material, and returning this numeric impact value as a numeric output;

said function of temperature being capable of generating a numeric impact value output in response to all input temperature values throughout the relevant temperature monitoring range of the device;

said function of temperature having an ability to distinguish between different environmental temperatures with a granularity that is small enough as to accurately approximate the impact of said environmental temperature on the detectable property of said material;

said interval of time between successive temperature sensor measurements being short enough as to allow said function of temperature to accurately follow time changes in said environmental temperature;

and wherein said microprocessor generates a running total of said numeric impact value output of said function of temperature over time;

and in wherein said microprocessor compares said running total to a reference value;

and wherein the microprocessor uses the result of said comparison to generate an output signal indicative of the fitness for use of said material;

whereby said material can be evaluated for fitness for use by storing said temperature sensor close enough to said material to as to enable the said temperature sensor to monitor the temperature history of the material;

whereby the remaining life of said material is evaluated in accordance with said output signal.

25: (New) The device of claim 24, in which the output signal is a visual output signal.

26: (New) The device of claim 24, in which the output signal is chosen from the group of visual output signals, vibration signals, sonic signals, radio frequency signals, electrical signals, or infra-red signals.

27: (New) The device of claim 24, further containing means to enable the function of temperature and reference value to be automatically programmed into an assembled device.

28: (New) The device of claim 24, in which said device additionally contains means to allow the function of temperature and reference value to be automatically programmed into an assembled device, said automatic programming means selected from the group consisting of replaceable memory chip, electronic data transfer, infrared data transfer, or radio frequency data transfer.

29: (New) The device of claim 24, in which the device is continually powered throughout its use lifetime, and the power means is chosen from the group of battery, storage capacitor, thermal, photoelectric, AC power, or radio frequency means.

30: (New) The device of claim 24, in which the function of temperature has a temperature resolution granularity of 10 °C or smaller, and the time intervals between successive temperature sensor measurements has a time resolution granularity of 2 hours or smaller.

31: (New) The device of claim 24, in which the display means convey information pertaining to the fractional remaining stability lifetime of material that has not yet expired, or the fractional completion of a time-temperature dependent incubation reaction.

32: (New) The device of claim 24, incorporated into a material dispensing device, in which the time-temperature device signals if the material should be dispensed or not depending upon the acceptability of the material's thermal history.

33. (New) A method for rapidly determining the fitness for use of a material, said method comprising;
storing said material in association with a unitized electronic time-temperature indicator device;

said material being external to said unitized electronic time-temperature indicator device;
said device containing computational means, and a temperature measurement means;
wherein said device periodically samples the temperature of said material's environment
and computes a function of temperature that is continually operative throughout the
relevant temperature monitoring range of the device;
and wherein said function of temperature approximates the impact that the relevant
temperature, for that period's length of time, has on a detectable property of said material;
and wherein said computational means generate a running sum of said function of
temperature over time;
and wherein said function of temperature resides with said unitized device;
and wherein the granularity of the function of temperature is small enough, and the
frequency of time measurements is often enough, as to substantially approximate the
impact of time and temperature on the detectable property of said material;
and in which said running sum is compared to a reference value, and the result of said
comparison is used to generate an output signal indicative of the fitness for use of said
material.